EFG Senior - Influenza burden assessment in adults aged of 65 years and more visiting a general practitioner for acute respiratory illness in France

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General

Identification

Detailed name	Influenza burden assessment in adults aged of 65 years and more visiting a general practitioner for acute respiratory illness in France
Sign or acronym	EFG Senior
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 908370

General Aspects

Medical area	General practice Infectious diseases Pneumology
Others (details)	Influenza
Keywords	elderly subjects, epidemiology

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private

Details	GSK laboratory
Governance of the database	
Sponsor(s) or organisation(s) responsible	LABORATOIRE GSK
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	An administrative base or a register
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	All of the general practitioners in the GROG network monitoring the age group of patients aged 65 years and older can participate. Each investigator will have to include, during the entire epidemic period (equivalent to the period of inclusion), the first 7 patients that meet the eligibility criteria.
Database objective	
Main objective	Describe and compare the burden of acute respiratory infections (IRA) linked to influenza virus, in terms of morbidity and medical consumption, according to the vaccinal status, in those 65 years and older spontaneously consulting in general practice
Inclusion criteria	? Patient aged 65 years or older ? Patient having an acute respiratory infection defined as a clinical presentation combining the abrupt appearance of respiratory signs (coughing, rhinitis, coryza) in the context of acute infection (fever, asthenia, headache, myalgia, etc.), in less than 48h. ? For patients 80 years and older, the clinical presentations can associate other general signs

	(mental confusion, dehydration, anorexia, digestive disorders, general malaise, body aches, headache) and respiratory signs (from rhinitis to pneumopathy)
Population type	
Age	Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	93
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Phone interview
Biological data (detail)	nasal sample

Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Each investigator will have to include, during the entire epidemic period (equivalent to the period of inclusion), the first 7 patients that meet the eligibility criteria. The investigator will inform patients who have accepted the study, of the objectives of the study using the information notice and will have them sign an explicit consent form. He will then complete the doctor's inclusion questionnaire and will remit the follow-up logbook to the patient, explaining to the latter how to complete this logbook. He must notify the logistics center of the inclusion via fax. The investigator will take a nasal sample and will send it to the reference laboratory according to the study's sampling protocol. In order to control any bias in the selection of patients, a non-inclusion registry will be set up. The investigating doctor will be asked to complete this registry, for all of the patients that meet the eligibility criteria who are not included in the cohort and to fill in the reason for non-inclusion, whatever it may be.
Participant monitoring	Yes
Details on monitoring of participants	Patient follow-up will take place by telephone (or during a visit) between 7 and 10 days and between 28 and 31 days after the inclusion visit, by the investigator, regardless of the patient's vaccinal status and the result of the virological tests. A questionnaire at the end of the study will also be completed by the investigator at the end of the period of the epidemic period, in order to follow any complications and/or superinfections linked to the influenza, and to inform the patients who have left the study. As for the patients, they will, starting on the day of their inclusion in the study, a follow-up logbook until they are cured or up to 28 days
Links to administrative sources	No

Promotion and access

Promotion Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications are planned
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only